abstract submitted in the parent '165 application. Also enclosed is a copy (as submitted in the parent '165 application) of the marked-up copy of the substitute specification which shows the changes made. The enclosed substitute specification and abstract do not include new matter. Thus, Applicant requests entry of the substitute specification and abstract in this application. Applicant notes that the enclosed copy of the substitute specification has been marked on page 1 to correct the attorney docket number.

In this Response, Applicant requests amendment to the first paragraph on page 1 of the substitute specification in the "Related Applications" section. Specifically, the substitute specification has been amended to refer to the parent application, U.S. Application Serial No. 09/316,165.

Applicant requests amendment to the paragraph bridging pages 1 and 2 of the substitute specification as set forth above. This amendment to the substitute specification merely corrects a typographical error in the U.S. patent number in that paragraph. The correct U.S. patent number is 4,656,813.

Applicant also requests amendment to the paragraph bridging pages 4 and 5 of the substitute specification as set forth above. The Amendment to pages 4 and 5 merely clarifies the description of Fig. 2C and does not add new matter. As shown in Fig. 2C, nozzles 104 and 107 provide air to the film FST. Nozzles 103, 105, 106, and 108 remove the air from the film FST. See the arrows indicating the direction of air flow through the nozzles in Fig. 2C.

Claims 16-50

Turning to the claims, claims 1-15 have been cancelled without prejudice and claims 16-50 have been added. Claims 16-34 correspond to claims 28-46, respectively, of the parent '165 application which were pending when the '165 application became abandoned. Claims 35-50 are new claims.

Independent claims 16 and 34 have been revised relative to claims 28 and 46 of the parent '165 application to clarify the claimed invention. Claims 16 and 34 call for the step of dry cleaning the printed film by directing air flow across surfaces of the film and flowing particles removed from the surfaces and the air out through a nozzle such that the film is not touched during dry cleaning. One example of the claimed dry cleaning step is shown in Fig. 2C. The printed film FST is dry cleaned by directing air flow across surfaces of the film. For example,

air from nozzles 104 and 107 flows across the surfaces of the film. The air removes particles from the film surfaces and carries the particles away through a nozzle. For example, the air flows away from the film through nozzles 103, 105, 106, 108. See the substitute specification at page 4, line 24-page 5, line 4.

Applicant's invention which includes the dry cleaning step provides advantages. For example, existing systems have used a liquid to wash the film and a drying phase to dry the washing liquid. Applicant's inventive method does not require the washing liquid or the wash liquid drying phase. Furthermore, Applicant's dry cleaning step can eliminate the use of an ultraviolet radiation sterilization step. See the substitute specification at page 5, lines 9-11.

Applicant notes that the term "gimbal" has been removed from the claims in reference to aligning the film for folding.

Rejections under 35 U.S.C. § 112, first paragraph and § 103 (a)

Turning to the Office Action, in Office Action paragraph 2, claims 5, 7 and 15 were rejected under 35 U.S.C. § 112, first paragraph. In Office Action paragraphs 6-11, various rejections under 35 U.S.C. § 103(a) were entered based on Baldini, et al. (US 4,656,813), Fabricus (US 5,069,017), Takegaki, et al. (US 5,606,844), Duffy et al. (US 5,129,212), Madsen (US 3,451,403), Ogata (GB 2142282 A), Brennan, et al. (US 4,587,793), and Aindow, et al. (US 5,934,043). A similar § 112, first paragraph, rejection was entered in the parent '165 application in an office action dated February 18, 2000. Also, similar § 103 rejections were entered in the parent '165 application in an office action dated August 10, 2000.

Those § 112, first paragraph, and § 103 rejections were overcome in the parent '165 application by revising the claims and amending the specification. In the present application, the claims have been revised and the specification amended similar to the revisions and amendments made in the parent '165 application. Accordingly, Applicant respectfully submits that the § 112, first paragraph, and § 103 rejections have been overcome.

Rejection under 35 U.S.C. § 112, second paragraph

In Office Action paragraph 4, claims 2-7 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The § 112, second paragraph, rejection merely

identifies typographical errors in the claims. The claims have been revised and the typographical errors corrected. Accordingly, Applicant respectfully submits that this rejection has been overcome.

Further remarks in view of the parent '165 application

Applicant submits that independent claims 16 and 34 are distinguished from the prior art for at least the reason of the dry cleaning step. For example, Worden et al., U.S. Patent No. 4,731,980, shows and describes an air knife 97 positioned at about a location where a web 20 exits a sterilization section 100. The air knife 97 is provided to vaporize any residual sterilizing medium. Also, the air knife 97 provides sterile air from a vent 72 into a sterile chamber to help maintain a positive sterile air pressure. See Worden et al., column 7, lines 21-26 and Figs. 1 and 5. Nowhere does Worden et al. disclose or suggest that the air knife, which vaporizes sterilization medium, dry clean the film by directing air flow across the surface of the film and flowing particles removed from the surface and the air out through a nozzle such that the film is not touched during dry cleaning.

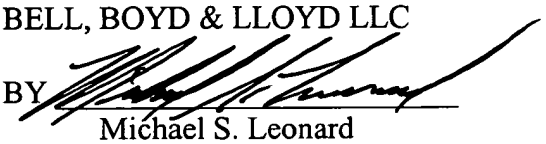
Applicant respectfully submits that it would not be obvious to modify Worden et al. or rely on Worden et al. to use the air knife 97 as Applicant's dry cleaning step. The purpose of the Worden et al. air knife 97 is to vaporize any residual sterilizing medium after cleaning the film and sterilizing the film. See Worden et al., column 6, lines 37-45 and column 7, lines 21-26. Using the Worden et al. air knife for Applicant's dry cleaning step would be contrary to the sterilizing medium vaporization purpose of the air knife because the film in Worden et al. has already been cleaned prior to the air knife.

Applicant submits that all pending claims are allowable.

Attached hereto is a marked-up version of the changes made to the substitute specification by the current amendment. The attached page is captioned "**Version with Markings to Show Changes Made.**"

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY 

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Dated: January 2, 2003

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Please amend the paragraph in the "Related Applications" section on page 1 of the substitute specification to read as follows.

This Application is a continuation of application serial number 09/316,165 filed May 21, 1999 which is a continuation of International Application No. PCT/IB97/01458, filed November 18, 1997. U.S. Serial No. 09/316,165 and International Application No. PCT/IB97/01458 ~~is~~ are hereby incorporated herein by reference, and made a part hereof.

Please amend the paragraph of the substitute specification at page 1, line 17-page 2, line 2 to read as follows.

Numerous prior art systems for manufacturing flexible containers, or bags, for use with infusion solutions in the medical field are known. For example, U.S. Patent No. ~~4,456,813~~ 4,656,813, describes a system for industrial production of these types of bags. These bags are sometimes generally referred to as form, fill and seal (F.F.S.) containers. These bags typically have a laminated construction and include a valve to accommodate various connectors of an infusion apparatus, such as a luer-type valve. The bags are typically sterilized during or after the manufacturing process. Sterilization of a bag that incorporates various design features, such as valves, can be difficult. The manufacturing and sterilizing process becomes even more difficult with present day bags that may be required to have additional features, such as means for bag suspension, complex valves, or twin-valve systems. These features create areas of the bag that are difficult to access by a sterilization solution during the sterilization process. This can cause variation in the sterilization times of these areas, which in turn can cause incomplete or ineffective sterilization. This variation can also have an effect on the proper selection of sterilization solution dosages.

Please amend the paragraph of the substitute specification at page 4, line 24-page 5, line 6 to read as follows.

Block 3 of FIG. 1 represents a washing station phase that comprises a single dry washing stage. The film entering the dry washing stage is labeled FST and the film exiting the dry washing stage is labeled FSTL, as shown in FIG. 1. The dry washing stage does not allow the film to contact any liquids or supports of the system. A preferred embodiment of the washing stage is represented in FIGS. 2B and 2C. In this embodiment, the washing stage is formed by two superimposed chambers 101 and 102 forming a central slot for printed film FST to pass therethrough. The printed film FST is suspended and subjected to filtered air AF flowing from ~~three~~ nozzles ~~103,~~ 104 and ~~105~~ 107. The air flows over the printed film FST and carries away any particles or impurities from the printed film FST. The air flows out through nozzles 103, 105, 106,~~107~~ and 108. The stations represented by blocks 2 and 3 can operate and handle a plurality of film configurations, such as in the case of using two reels B and B' of equal length, or using a single reel B" having a width n times greater than B or B'.

SYSTEM TO FORM FILL AND SEAL FLEXIBLE BAGS

TECHNICAL FIELD

The present invention concerns a system to form, fill and seal (F.F.S.) Containers of flexible plastic materials, in particular sterilizable bags containing solutions for the administration of infusion solutions. [The system generally includes the phases of: (1) feeding from at least one reel a plastic and flexible material in the form of a film or pellicle, preferably multilayer, forming the bag; (2) printing the material pulled from the reel; (3) winding the printed material; (4) washing the printed material; (5) aligning and folding the printed and washed film; (6) welding the folded film in a first direction; (7) feeding and applying valves on the surface of the folded and welded film; (8) making a second welding in a second direction; and, (9) cooling and cutting the bags to send to them for overwrapping and sterilizing.]

RELATED APPLICATIONS

This Application is a continuation of International Application No. PCT/IB97/01458, filed November 18, 1997. International Application No. PCT/IB97/01458 is hereby incorporated herein by reference, and made a part hereof.

BACKGROUND OF THE INVENTION

Numerous prior art systems exist for manufacturing flexible containers [and filling them with liquids], or bags, for use with infusion solutions in the medical field are known. [However, only commonly assigned] For example, U.S. Patent No. 4,456,813 (corresponding to European Patent No. 142,758) describes a [first efficient] system [that is substantially automatic] for the industrial production of these types of bags [with valves and comprising the phases described herein]. [For quite some time this system has permitted the achievement of

arge industrial targets. Nevertheless, with all its merits, it has shown some limits. For example, present day lemands and the requirements of the health authorities call for several further means, such as the application of : means for bag suspension and the use of technologically advanced and complex valves. These and other 'alves can have zones difficult to access, i.e., cavities that would require extremely long sterilization times for :afe sterilization, as compared with the time required to sterilize only the container. For example, sterilization)f the container can be accomplished in about 10 minutes in an autoclave at 120°C, however, sterilization of the .alve requires much longer times that are not industrially acceptable. In fact, water could reach the cavities :ither th rough permeability of the bag wall on which the valve is welded, or th rough the external surfaces of he valve itself. If the volume of the cavity is small, the danger is small, but if the volume of the bag is large, he danger is prohibitive. In addition to the increased sterilization times, there would always be uncertainty :bout the effectiveness of the treatment. Furthermore, in the conventional system several difficulties were ncurred in sanitizing the various mechanisms, one example being that of dosing. To dose, the quantity of :olution necessary to fill the bag required additional time that was not only excessive, but lacked precision. \ccordingly, a system which minimizes or eliminates these drawbacks is preferred.] These bags are sometimes generally referred to as form, fill and seal (F.F.S.) containers. These bags typically have a laminated construction and include a valve to accommodate various connectors of an infusion apparatus, such as a luer-type valve. The bags are typically sterilized during or after the manufacturing process. Sterilization of a bag that incorporates various design features, such as valves, can be difficult. The manufacturing and sterilizing process becomes even more difficult with present day bags that may be required to have additional features, such as means for bag suspension, complex valves, or twin-valve systems. These features create areas of the bag that are difficult to access by a sterilization solution during the sterilization process. This can cause variation in the sterilization times of these areas, which in turn can cause incomplete or ineffective sterilization.

This variation can also have an effect on the proper selection of sterilization solution dosages.

Therefore, it is an object of the present invention to provide a system and associated method for manufacturing F.F.S. containers of flexible plastic materials that can be easily sterilized without the disadvantages of previous systems and methods.

It is also an object of the present invention to provide a system and method for manufacturing F.F.S. containers of flexible plastic materials that are characterized by high manufacturing efficiency, sterilization reliability, and precision.

It is a further object of the present invention to provide a less expensive and space-efficient system for manufacturing F.F.S. containers of flexible plastic materials.

These and other objects will become readily apparent after review of the specification, drawings, and accompanying claims.

SUMMARY OF THE INVENTION

The first aim of the present invention is to provide a very advanced system that does not have the disadvantages of previous systems and is characterized by high efficiency, reliability, hygiene security and maximum precision. Another aim of the invention is to provide the previous system with more efficient, less expensive and more compact treatment means. These and other aims are obtained in the system with the present invention.]

The system of the present invention includes a method of manufacturing form, fill and seal (F.F.S.) containers, or bags, made from flexible plastic materials. The system and associated method generally include the steps of: (1) feeding from at least one reel a plastic and flexible material in the form of a film or pellicle, preferably multilayer, for forming the bag; (2) printing the material pulled from the reel; (3) winding the printed material; (4) washing the printed material; (5) aligning and folding the printed and washed film; (6) welding the

olded film in a first direction; (7) feeding and applying valves on the surface of the folded and welded film; (8) naking a second welding in a second direction; and, (9) cooling and cutting the bags to send to them for verwrapping and sterilizing.

BRIEF [SUMMARY] DESCRIPTION OF THE DRAWINGS

The different aspects and advantages of the invention will be seen better in the following description of the forms of realization (illustrative and not limiting) shown in the accompanying figures, where:

- fig. 1 is a block diagram of the system of the present invention.
- fig. 2 is a planar representation of a first kinematics scheme of the realization of the process of fig. 1;
- fig 2A is the enlarged representation of a variant of a portion of fig. 2;
- fig. 2B and 2C are two views in partial and schematic perspective of a dry cleaning means of the present nvention;
- fig. 3 is a schematic and partial perspective view illustrating one arrangement of the stages and means for the realization of the process in fig. 1;
- figs 4 and 5 are two frontal views, partially in section, of two valves of the present invention;
- figs 6 and 7 are schematic top views of bags with the valves of figs 4 and 5 and with a ring in the suspension hole of the present invention;
- fig. 8 is a partially cross-sectioned view of a means of humidifying the valves of the bags of the present invention;
- fig. 9 is the scheme of a high precision liquid dosing means of the present invention;
- fig. 10 is a lateral schematic view of the filling portion of the actuating machine, incorporating the dosing means of fig. 9;
- fig. 11 is a lateral view of an arrangement of the print station of the present invention;

fig. 12 is an perspective view of the valve welding station of the present invention;

fig. 13 is an perspective view of the final welding and molding block of the present invention.]

FIG. 1 is a block diagram of the system of the present invention.

FIG. 2 is a schematic diagram of an embodiment of the system of FIG. 1.

FIG. 2A is a partial view of a variation of the embodiment disclosed in FIG. 2.

FIG. 2B is a partial perspective view of an embodiment of a dry cleaning means of the present invention.

FIG. 2C is a partial perspective view of the embodiment of the dry cleaning means of FIG. 2B.

FIG. 3 is a perspective view of a schematic representation of a preferred embodiment of the system of FIG. 1.

FIG. 4 is an elevational view, partially in section, of a first embodiment of a two-valve structure of a bag manufactured according to the method of the present invention.

FIG. 5 is an elevational view, partially in section, of a second embodiment of a two-valve structure of a bag manufactured according to the method of the present invention.

FIG. 6 is a top plan view of a bag manufactured according to the method of the present invention and incorporating the valve assembly of FIG. 4.

FIG. 7 is a top plan view of a bag manufactured according to the method of the present invention and incorporating the valve assembly of FIG. 5.

FIG. 8 is a schematic view in partial cross-section of a humidification means for humidifying the valves of the bags manufactured according to the method of the present invention.

FIG. 9 is a schematic view of a high precision liquid dosing means for filling the bags manufactured according to the method of the present invention.

FIG. 10 is a schematic view of a filling portion of an actuating machine of the system of the present

invention that incorporates the dosing means of FIG. 9.

FIG. 11 is an elevational side view of an embodiment of a total print station of the system of the present invention.

FIG. 12 is a perspective view of a valve welding station of the system of the present invention.

FIG. 13 is a perspective view of a final welding and molding block of the system of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[With reference to figs 1 and 2 the system according to the invention is substantially representable with at least 5 stations, each involving one or more treatments.]

[In particular] Referring to FIG. 1, block 1 [shows the stage, respectively] represents the supplying station [for the feeding of the] that feeds a film F from a first reel B[;] [t]The dashed line rectangles B' and B" represent optional reel configurations. [show the possibility of placing in station 1 at least a second reel B' in parallel to the first reel B and of the same width as that, or else a reel B" of a width n times the width of B or B'. Associated with the unwinding reel RS is a means for tension adjustment bearing a braking means DF.] The reel B' can be placed in addition to and parallel to the first reel B. The reel B' is preferably of the same width as the first reel B. Alternatively, the reel B" can be used in lieu of reels B or B'. In this case, the reel B" is preferably n times the width of B or B'. Referring to FIG. 2, a tension adjustment and braking mechanism DF is provided in communication with the reels B and/or B', or B".

[According to another aspect of the invention] [b]Block 2 of FIG. 1 represents [shows ~a~ station of] a total printing (TP) [on line] station [(]2a[)] that is followed by [the] an accumulation station [(]2b[) of the thus completely printed film on line. The TP station now includes a hot printer that uses a hotpress as the impression means and that lays on the bag, from a pigmented film, the characters placed on a cliché. The station TP is preset

to obtain the printing of the prescription, the lot number and the data of the daily production. Furthermore through the print menu it is possible to set up the bag format (from 50 cc to 5,000 cc), the temperature and speed and all the numerous parameters needed for the printing of the bag itself]. The accumulation station 2b accumulates the printed film in-line with the TP station 2a. The TP station 2a includes a hot printer that utilizes a hot press and a pigmented film to imprint characters on the film. The characters of the printed matter are on a cliche of the hot printer. The TP station 2a is preset to obtain the character printing information, such as a prescription, a lot number, or data relating to the production. Furthermore, a print menu incorporated into the TP station 2a allows for the setup of various printing parameters, such as bag size (50cc to 5,000cc), temperature, speed, and the like.

[Block 3 shows the washing station phase that now of a single dry washing stage. There is no contact with liquids and supports. One of the preferred washing means is represented in figs 213 and 2C. It is formed by two superimposed chambers 101 and 102 with a central slot for the printed film FST that is suspended and subjected to filtered air AF flowing in from three nozzles 103, 104 and 105. The air then flows out through nozzles 106, 107 and 108 after it has flowed over, and hence washed, particles and impurities from the printed film FST as shown in fig. 2C. In the case of using more reels B, B' etc. of equal length, or a reel B" of a width n times greater than the previous ones, the stations 2 and 3 are able to operate contemporaneously on a plurality of films.]

Block 3 of FIG. 1 represents a washing station phase that comprises a single dry washing stage. The film entering the dry washing stage is labeled FST and the film exiting the dry washing stage is labeled FSTL, as shown in FIG. 1. The dry washing stage does not allow the film to contact any liquids or supports of the system. A preferred embodiment of the washing stage is represented in FIGS. 2B and 2C. In this embodiment, the washing stage is formed by two superimposed chambers 101 and 102 forming a central slot for the printed film FST to pass therethrough. The printed film FST is suspended and subjected to filtered air AF flowing from three

nozzles 103, 104 and 105. The air flows over the printed film FST and carries away any particles or impurities from the printed film FST. The air flows out through nozzles 106, 107 and 108. The stations represented by blocks 2 and 3 can operate and handle a plurality of film configurations, such as in the case of using two reels B and B' of equal length, or using a single reel B" having a width n times greater than B or B'.

[Block 4 shows the treatment of the printed film on line and dry washed, FTSL, in four subphases including: accumulation (4b) of FSTL, gimballing alignment (4d), folding (4e), and towing (4f).]

Block 4 of FIG. 1 represents a station comprising four substeps for handling the printed and dry washed film FSTL. The four substeps comprise accumulation 4b, gimballing alignment 4d, folding 4e, and towing 4f. Compared to prior art systems, a drying phase is not needed because dry washing is utilized. Furthermore, a sterilization step that utilizes ultraviolet radiation has also been eliminated.

[In the system according to the present invention there has been the advantageous elimination of not only the drying phase (4a) (due to dry washing) but also the phase (4c) of sterilization with ultraviolet rays UVA as described in US Patent N° 4,456,813. As can now be seen station four is extremely more compact, efficient and reliable. The few means for performing these operations are thus the rollers (4b), (4d), (4e, 4e' with the folding prism PR) and therefore (4f). The old squeezing rollers (4a) and the UV plate (4c) associated with the rollers having been eliminated.

The functioning of the alignment rollers (4b), the folding prism PR inserted, between the rollers (4e) and (4e') and, lastly, the towing roller (4f) cooperating with the second folding roller (4e') is now faster and safer (also because there are no stops and interruptions in the new, only four-phase, station 4).

Station 5 can now be considered "revolutionized" compared with that of our previous US patent N° 4,656,813. In fact in station 5, bag formation by vertical and horizontal welding and application of. valve(s) and suspension rings, there are now found only substations of longitudinal (vertical) welding (5a) and valve application (5b).]

Referring to FIG. 2, the printed and dry washed film FSTL is first aligned by alignment rollers 4b. First

and second folding rollers 4e and 4e' facilitate a folding prism PR therebetween for folding the printed and dry washed film FSTL. A towing roller 4f cooperates with the second folding roller 4e' to complete the handling station.

Block 5 of FIG. 1 represents the bag formation step of the manufacturing process. The bag formation step involves vertical welding of the film as well as the attachment of one or more valves. The bag formation step comprises a vertical welding substation 5a and a valve attachment substation 5b. The bag is formed and the valves are attached by welding. FIGS. 4 and 5 show two valve structures that can be attached to the bag. Such valves are disclosed in U.S. Patent No. 4,467,003.

[Figs 4 and 5 show two valve structures of the types EMO-LUER and TWIN VALVE. They consist of a cap T, a valve core CV, a rubber plug GP and two cavities CA1 and CA2. In the "TWIN" valve TO indicates the part to be removed at the moment of using the product, guaranteeing the sterility of the product contained within, ZF indicates the twist-off fracture zone. The EMO-LUER valve of fig. 5 consists of the valve core EPO-L, the rubber plug GP, the cap TT, the perforator P and the warranty seal SG that will be broken at the moment of use; OR indicates the sealing gasket. These valves are in themselves already known from the disclosure of Applicant's US Patent N°4,467,003. Shown in fig. 6 is a bag SA with a TWIN-VALVE valve TV at a transverse extremity, and a suspension hole in the opposite wall. Shown in fig. 7 is a bag SA with an EMO-LUER valve (VEM) on the longitudinal side and with a suspension ring AS on the other longitudinal side.

Station 5 now also comprises: (x) a vibrator (5b1) for feeding the valves and, according to the most notable aspect of the invention (y) a spray wetting-means (5b2) for valve cavities; (z) a means (5b3) for the detection and control of the wetting; (j) a means (5c) for making a bag suspension hole; and (w) a means (5f) for the application of a suspension ring (in addition to, or as an alternative to, the said hole), including also a vibrator (5f1) for the supplying of the said ring.]

In more detail, the bag formation step of block 5 comprises a vibrator 5b1 for feeding the valves during

the assembly process, a humidification means, such as a spray wetter 5b2, for wetting the valve cavities, a detection and controlling means 5b3 for the spray wetter, a suspension hole forming means 5c that forms a suspension hole in the bag, and a suspension ring application means 5f that applies suspension rings to the suspension hole of the bag. A vibrator 5f1 is also included for feeding the suspension rings during the assembly process.

[According to an aspect of the invention the valve welder is an ultrasound one with open ring control of position and approach speed. For such a purpose the original welding system disclosed in US Patent N° 4,656,813 has been greatly improved by the introduction of a continuous checking of the position and speed of the welding head (5b) ("sonotrode") during its approach to the anvil (represented by dashes). Fig. 12 shows the relative block (5b) comprising a position transducer (81), a cylinder (82), a slide (83), the sonotrode (84), and a transducer (85). With an algorithm of the PID type sampled to a thousandth of a second, an optimization was carried out of the speed and the acceleration (deceleration) of the sonotrode\anvil impact, the aim being to make the whole welding operation as soft as possible (and hence reliable).]

In a preferred embodiment of the invention, the valve welder is an ultrasound welder with open ring control of position and approach speed. Fig. 12 shows the valve attachment station 5b as a welding and molding station. The valve attachment station 5b comprises a position transducer 81, a cylinder 82, a slide 83, a sonotrode 84 (welding head) and a transducer 85. The system allows for continuous checking of the position and speed of the sonotrode 84 at substation 5b with respect to an anvil (not shown). With a PID (Proportional Integral Derivative) algorithm sampled to a thousandth of a second, the speed and acceleration/deceleration of the sonotrode/anvil impact was optimized. This allows the welding operation and the resulting weld to be optimized with respect to the bag material utilized.

[In a further aspect of the invention the dosing of the filling liquid RIEM is done with very great precision due to

a station SP, substantially automatic, comprising at least electropneumatic valves (60) and (62) fed by (61) and ~ a processing switchboard (63). The dosing valve has a double electropneumatic thrust and permits the operating (opening/closing) of the dosage means in a time of 3 to 5 thousandths of a second, allowing a precision of +/-1 cc per dosage quantity.]

Referring to FIG. 1, station SP fills the bag with the proper dose, or volume, of the liquid RIEM. The station SP is a precise, substantially automatic station that includes electropneumatic valves 60 and 62 that are fed by line 61. A processing switchboard 63 allows for control of the valves 60 and 62. The valves 60 and 62 provide a double electropnuematic thrust and permit opening and closing of the valves 60 and 62 in a time of 3 to 5 thousandths of a second, which provides a dosage tolerance of +/- 1 cc per dosage quantity.

[In the preferred embodiment the means is controlled by the number of impulses coming from a lobed flowmeter with Halls effect. Fig. 10 shows the arrival point AIC of the tubular feeding connection from the solution (not represented), the dosing valves of fig. 9, the broadened extremity EA of the supply tube TE -within a bag SA in the filling phase, followed by the next bag SAC (also not yet sealed at the top, still to be filled):]

In a preferred embodiment, the valves 60 and 62 are controlled by pulses generated by a lobed flowmeter that utilizes a Hall effect. Figs. 9 and 10 depict the station SP in more detail.

[Still another characteristic of the invention lies in the shaping of the bags (contemporaneously with horizontal welding), through the regulation and control of the temperature of two mobile bars (71), (73) (fig. 13) that are heated by highly efficient electric heating elements, and able to compress, weld and thermoform the bags, eliminating any possible ears. Besides the hot vulcanized bar (71), the means of fig. 13 includes a cold bar contrasting the cutting edge (72), the second hot forward bar (73), a cutting edge support (74) and a cold support bar of the cutting edge (75).]

FIG. 13 depicts a mechanism for shaping the bags contemporaneously with horizontal welding via movable bars 71 and 73. The bars 71 and 73 are heated by electric heating elements and allows the bars 71 and

73 to compress and thermoform the bags without the formation of ears. The mechanism of FIG. 13 also includes a non-heated cutting edge 72 and a cutting edge support 74.

[Again use is made of a PID (Proportional, Integral Derivative) type algorithm, dynamically modified to optimize temperature control, for example on twelve interlaced points. The cooling of the welding follows immediately through the action of cooled bars (e.g. of the type 72, 75 of fig.13) that, besides cooling and blocking the welding folding process, cuts the bags themselves to measure.]

A PID type algorithm is used to control the temperature of the bars 71 and 73. For example, the temperature can be controlled on twelve selected points on the bars 71 and 73. The non-heated bars 72 and 74 provide immediate cooling of the thermoformed area of the bag. The bars 72 and 74 also cut the bags to the desired dimension.

[As a notable aspect of the invention the humidification of the cavities *CM CA2 of* either the EMO-LUER or TWIN VALVE 'of figs 4 and 5 can be carried out in various ways, for example with the means of fig. 8, comprising a valve V1, a fluxstate FLU, a nebulization nozzle US, a piston PA to move the US served by a sensor SEP, a bridging circuit for the observation of the electric conductability in the already wet cavity for the controlling of the correct humidification, and a discharge channel for the wetting liquid CSLB.]

The valve cavities depicted in FIGS. 4 and 5 can be humidified, or wetted, by use of the mechanism depicted in FIG. 8. The mechanism includes a valve VS, a fluxstate FLU, a nebulization nozzle US, a piston PM to move the nozzle US, a sensor SEP that controls the piston PM, a bridging circuit for the measurement of the electrical conductivity in the wetted cavity that provides humidification control, and a discharge channel for the wetting liquid CSLB. The nozzle US includes a lance for penetration into the valve cavities. The wetting liquid CSLB is preferably distilled water, a physiological solution, or hydrogen peroxide. The wetting liquid is used to sanitize and detect electric conductability in the cavities.

[Even though the invention has been described with reference to the embodiment forms represented in the accompanying drawings it is obvious that it is not limited to these embodiments but is susceptible to all the variants, modifications, substitutions and such like that, being within the reach of the person skilled in the art, fall naturally within the spirit and scope of the following claims. In fact the described means of dry washing, total printing, humidification etc. can be substituted by equivalent commercial means. Furthermore the system according to the invention foresees the possibility not only of welding one or more valves onto the same bag but also of working on two series of bags (odds and evens) and of applying a type of valve, a ring or a suspension hole on the odd and even bags alternatively. The film and pellicle F (fig. 1) forming the bags (SA with valves and suspension means) are preferably multilayer, consisting of (co)polymers of laminated olefins, amides, esters etc. (US patent N° 4,326,574), but better still coextruded, particularly those according to the Applicant's demands for European patent N°0658421 and International patent WO 95/16565.

Indeed optimal results have been obtained with coextruded film based on two external layers (homogeneous chemically) of ethylene copolymers (PE) propylene (PP) that themselves differ only in the PE content, or of two chemically diverse layers e.g., polyethylenelpolypropylene. The adhesion of the two layers is ensured by an appropriate coextruded binding, also polyolefinic. By cautiously choosing the composition of the external layers, the binding and hence the adhesion between the said layers, and any possible temperature difference between the welding bars etc. bags can be obtained with optimal values of welding resistance, resistance to shocks particularly including dropping, transparency, sterilizability etc.. The coextruded films can have additional layers, these also being coextruded or even laminated onto three-layer film (two external layers and that of the binding).]

The system of the present invention can be used to weld one or more valves onto the same bag or even welding valves only on a particular series of bags, e.g., even or odd numbered bags. The film F in FIG. 1 used to form the bags can be multilayer, comprising polymers or copolymers that include laminated olefins, amides, esters, or the like, as disclosed in U.S. Patent Number 4,326,574. Preferably, the film F is coextruded, such as

disclosed in Applicant's European Patent Application Number 0658421 and International Patent Number WO 95/16565.

Optimal results have been obtained with coextruded film based on two external layers of ethylene and propylene copolymers or of two chemically diverse layers, such as polyethylene/polypropylene. The adhesion of the two layers is ensured by an appropriate coextruded binding, which is also a polyolefin. By choosing the appropriate composition of the external layers, the binding and the adhesion of the layers can be optimized with respect to weld temperatures and weld resistance during manufacturing. Various properties of the bag material may also be optimized, such as strength of the bag and bag weld, transparency, sterilizability, etc. The coextruded films can also have additional layers that are themselves coextruded or laminated to the coextruded films.

While the specific embodiments have been illustrated and described, numerous modifications come to mind without significantly departing from the spirit of the invention and the scope of protection is only limited by the scope of the accompanying Claims.